

WAIVER OF AUTHORIZATION APPROVAL LETTER

In Compliance with section 164.512(i)(2)(iv)(C) of the HIPAA privacy rules, a representative from Medical IRB#2 has reviewed the use of Protected Health Information (PHI) by expedited review.

The expedited review was conducted in accordance with 45CFR 46.110 (b)(2), the minor changes provision.

The IRB protocol #64259 meets the criteria for the waiver of authorization according to 164.512(i)(2)(ii), which are as follows:

The use or disclosure of protected health information involves no more than a minimal risk to the privacy of the individual based on:

-An adequate plan to protect the identifiers from improper use/disclosure

-An adequate plan to destroy the identifiers at the earliest opportunity consistent with the research justification unless health, research or legal justifications to retain the identifiers.

-An adequate written assurance that the PHI will not be reused or disclosed to any other person unless required by law, authorized oversight or as permitted by the following subpart:

-the research could not practicably be conducted without the waiver or alteration;

and

-the research could not practicably be conducted without access to and use of the PHI.

 MD/jch

IRB Designee

3/10/2021

Date

see blue.